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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,513	06/20/2000	Alan Collmer	19603/3306 (CRF D-2136B)	5828

7590 06/21/2004

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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/597,513	COLLMER ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-10 and 40-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-3 and 5-10* is/are allowed.

6)☒ Claim(s) *40-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-3, 5-10 and 40-51 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The objection to claims 2-5, 7 and 9-10 because they have an improper article at the start of the claim, is withdrawn in light of applicant's amendment to claim 1 that makes it allowable.

4. The objection to claims 2-3 as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form and to address the objection above, is withdrawn in light of applicant's amendment to claim 1 that makes it allowable.

5. The rejection to claims 1-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the phrase "wash conditions effective to remove DNA that binds non-specifically to the DNA molecule" is withdrawn in light of applicant's amendment.

6. The rejection to claims 6-7 and 10 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements is withdrawn in light of applicant's amendment to the claims.

Claim Rejections - 35 USC § 112

7. Claims 40-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set

forth in the Office action mailed 7 October 2003, as applied to claims 1-10. Applicant's arguments filed 12 April 2004 have been fully considered but they are not persuasive.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "a DNA molecule from a source other than *Pseudomonas syringae* pv *tomato*".

Applicant urges that because SEQ ID NO:1 represents the hrpW species from *Pseudomonas syringae* pv *tomato* and the remaining species will be from another pathogen, it is appropriate to consider the subject matter excluded from the scope of claim 40 (response pg 5).

This is not found persuasive because the specification claims all nucleic acids that hybridize to SEQ ID NO:1 and that encode a hypersensitive response elicitor other than those from various *Erwinia* species or *P.s.* pv *syringae* (see paragraph spanning pg 10-11); *P.s.* pv *tomato* is not among the hrp gene and sources on that list. The specification states: "The present invention relates to an isolated DNA molecule having a nucleotide sequence of SEQ. ID. No. 1" on pg 6. lines 24-25.

Applicant urges that the objected to language was introduced explicitly to exclude Lorang's sequence, which partially overlaps SEQ ID NO:1. Applicant urges that incorporation of Lorang into the specification does allow Applicant to exclude such matter from the scope of the genus (response pg 5).

This is not found persuasive because *P.s.* pv *tomato* is not among the hrp gene sources excluded in the paragraph spanning pg 10-11 of the specification.

Applicant cites *In re Johnson* to urge that written descriptive support for a subgenus does exist where both the excluded species and the genus are disclosed (response pg 6).

This is not found persuasive because the circumstances of *In re Johnson* are different from those in the instant case. In *In re Johnson* the specification listed a specific number of

specific choices for the compound, while the claims were limited to a smaller number of those specific choices (see 194 USPQ, pg 195). In the instant case, no specific number of specific choices for the source of the gene was disclosed in the specification; thus, *In re Johnson* is not analogous. Applicant is limited to the exclusions listed in the paragraph spanning pg 10-11 of the specification.

8. Claims 40-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids of SEQ ID NO:1 or encoding SEQ ID NO:2, does not reasonably provide enablement for nucleic acids that hybridize under conditions of unspecified stringency to SEQ ID NO:1 or for expression of nucleic acids that encode SEQ ID NO:2 or hybridize to SEQ ID NO:1 in plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 October 2003, as applied to claims 1 and 4-10. Applicant's arguments filed 12 April 2004 have been fully considered but they are not persuasive.

Applicant urges that claim 40 recites the hybridization conditions and the function of the encoded protein (response pg 7).

This is not found persuasive because the specification does not teach the sequence of the claimed nucleic acids.

Applicant urges that hybridization procedure in Examples 5 and 10 is a standard one and the conditions are disclosed, and that washes are typically done until no radioactivity is detected in regions of the membrane that do not contain DNA (response pg 7).

This is not found persuasive because washes can be done for less time or for more, and under different times, different DNAs will hybridize. The specification gives no guidance as to time for identification of the claimed DNAs.

Applicant urges that have shown that hrpW homologs exist in other Gram-negative pathogens; thus one of ordinary skill in the art would have expected HrpW to be widely distributed among Gram-negative pathogens. Applicant cites Guttman et al, 2003, to state that the Southern protocol of Sambrook was used (response pg 7).

This is not found persuasive because the specification must teach how to make the claimed DNAs, not how to find them.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1016:

> Conception of generalized approach for screening DNA library that might be used to identify and clone erythropoietin gene of then-unknown constitution is not conception of "purified and isolated DNA sequence" encoding human EPA, since it is not "definite and permanent idea of the complete and operative invention."

See *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

Applicant urges that they restriction mapped and did partial DNA sequence analysis for a DNA from *P.s.* pv *syringae*, in addition to showing that 11 other species were sources for the claimed DNAs (response pg 7-8).

This is not found persuasive because the sequence of the *P.s.* pv *syringae* gene is not provided. The specification also does not teach the sequence of the DNAs from the other 11 species. The specification must teach how to make the claimed DNAs, not how to find them.

Applicant urges that one of skill in the art would be able to routinely assay the function of the protein encoded by the DNAs (response pg 8).

This is not found persuasive because it is Applicant's job to teach if DNAs that hybridize to SEQ ID NO:1 encode hypersensitive response elicitor. Applicant has also not taught the structural elements common to the claimed genes but not to nucleic acids encoding other hypersensitive response elicitors.

9. Claims 40-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 October 2003, as applied to claims 1 and 4-10. Applicant's arguments filed 12 April 2004 have been fully considered but they are not persuasive.

Applicant urges that one of skill in the art would recognize that applicant was in possession of isolated hrpW-encoding nucleic acids from other than *P.s.* pv *tomato* because of their identification of the sequence of one species and demonstration that it hybridized to DNAs from other a wide range of Gram-negative species (response pg 8-9).

This is not found persuasive. Applicant is claiming DNAs from each of *P.s.* pv *glycinea*, *P.s.* pv *papulans*, *P.s.* pv *pisi*, *P.s.* pv *phaseolicola*, *P.s.* pv *tabaci*, *P.s.* pv *syringae*, *P. syringae*, *P. viridiflava*, *Ralstonia solanacearum*, and *Xanthomonas campestris*, but has not described the sequence of any of them, nor has Applicant deposited plasmids comprising the HrpW gene from any of those species in a depository. Thus, one of skill in the art would not recognize that applicant was in possession of isolated hrpW-encoding nucleic acids from other than *P.s.* pv *tomato*.

Applicant urges that the Written Description Guidelines do not state that one disclosed sequence cannot provide support for a genus. Applicant urges that the demonstration that the

variance within the claimed species is at a minimum given the recitation of hybridization and wash conditions (response pg 9).

This is not found persuasive because a description of the HrpW sequence from *P.s.* pv *tomato* does not provide support for the hrpW sequence from *P.s.* pv *glycinea*, *P.s.* pv *papulans*, *P.s.* pv *pisi*, *P.s.* pv *phaseolicola*, *P.s.* pv *tabaci*, *P.s.* pv *syringae*, *P. syringae*, *P. viridiflava*, *Ralstonia solanacearum*, and *Xanthomonas campestris*.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997) at pg 1406:

> ... A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.
> ... the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

Furthermore, the description of hybridization and wash conditions is only partial.

10. Claims 40-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 40 is indefinite in its recitation of the hybridization wash conditions because wash times are not recited. Because those times are not recited, it is unclear which DNAs are excluded and which excluded from the claimed DNAs.

Claim Rejections - 35 USC § 102

11. Claims 40-51 are rejected under 35 U.S.C. 102(a) as being anticipated by Tabakaki et al (1997, Devel. Plant Biol. 9:392-396). The rejection is repeated for the reasons of record as set

forth in the Office action mailed 7 October 2003, as applied to claims 1 and 4-10. Applicant's arguments filed 12 April 2004 have been fully considered but they are not persuasive.

Applicant submits a sequence alignment between the gene of Tabakaki et al and SEQ ID NO:1 and urges that because of the low homology between the two, they would not hybridize under the recited conditions (response pg 9-10).

This is not found persuasive because the wash conditions are not recited in the claims.

12. Claims 40-44 and 47-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Bauer et al (US Patent 5,850,015, filed June, 1995). The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 October 2003, as applied to claims 1 and 4-10. Applicant's arguments filed 12 April 2004 have been fully considered but they are not persuasive.

Applicant submits a sequence alignment between the gene of Bauer et al and SEQ ID NO:1 and urges that because of the low homology between the two, they would not hybridize under the recited conditions (response pg 10).

This is not found persuasive because the wash conditions are not recited in the claims.

13. Claims 1-3 and 5-10 are allowed.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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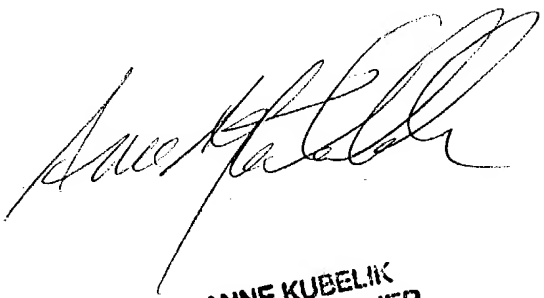
Anne R. Kubelik, Ph.D.
June 17, 2004



ANNE KUBELIK
PATENT EXAMINER